IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AVENTIS PHARMA S.A., SANOFI-AVENTIS U.S., LLC, Plaintiffs, v. APOTEX INC., APOTEX CORP., Defendants.	)	Civil Action No. 08-cv-496-GMS

APOTEX INC.'S ANSWER TO COMPLAINT FOR PATENT INFRINGEMENT

Defendant, Apotex Inc., by its attorneys, Duane Morris LLP, for its Answer to the Complaint for Patent Infringement filed by Aventis Pharma S.A. and sanofi-aventis U.S., LLC, states as follows.

THE PARTIES

1. Aventis Pharma S.A. is a French corporation with its principal place of business in Paris, France. Sanofi-aventis U.S., LLC is a Delaware corporation with its principal place of business in Bridgewater, New Jersey.

ANSWER: On information and belief, Apotex Inc. admits the allegations of paragraph 1.

2. Sanofi-aventis is in the business of developing, manufacturing, and selling a wide variety of consumer products, including pharmaceutical products. Sanofi-aventis U.S., LLC is the holder of approved New Drug Application No. 020-449 for the active ingredient docetaxel, which has the proprietary name Taxotere®. Taxotere® is sold by sanofi-aventis throughout the United States, and it has been approved by the FDA for seven indications. Worldwide, Taxotere® is marketed in over 100 countries and used for the treatment of, among other things, breast, lung, prostate, gastric, and head and neck cancer.

ANSWER: On information and belief, Apotex Inc. admits that sanofi-aventis is the holder of NDA 020-449, and that it sells Taxotere. Apotex Inc. lacks knowledge or information

sufficient to form a belief about the truth of the remaining allegations of paragraph 2, and therefore denies the same.

3. Upon information and belief, Defendant Apotex Inc. is a company organized and existing under the laws of Canada with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M91 1T9. Upon information and belief, Apotex Inc. is a wholly owned subsidiary of Apotex Pharmaceutical Holdings Inc. Upon information and belief, Defendant Apotex Inc. manufactures numerous generic drugs for sale and use throughout the United States, including this judicial district.

ANSWER: Apotex Inc. admits that Apotex Inc. is a Canadian company with a place of business at 150 Signet Drive, Toronto, Canada M9L1T9, that Apotex Inc. is a wholly owned subsidiary of Apotex Pharmaceuticals Holdings Inc., and that Apotex Inc. develops and manufacturers quality generic pharmaceuticals that are sold in numerous countries including the U.S. Apotex Inc. denies the remaining allegations of Paragraph 3.

4. Upon information and belief, Apotex Inc. has availed itself of the legal protections of the State of Delaware, having filed counterclaims seeking judicial relief from this Court in, among other cases, *Sanofi-Aventis. et al v. Apotex Inc. et al*, Civil No. 07-792.

ANSWER: Apotex Inc. admits that Apotex Inc. has filed counterclaims in cases in this district, including Civil Action No. 07-792. Apotex Inc. denies the remaining allegations of paragraph 4.

5. Upon information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of Delaware with a place of business at 2400 North Commerce Parkway, Weston, Florida, 33326. Upon information and belief, Apotex Corp. is a wholly owned subsidiary of Apotex Pharmaceutical Holdings Inc. Apotex Corp. is registered to do business in Delaware and The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware, 19801, is its registered agent in Delaware.

ANSWER: Apotex Inc. admits that Apotex Corp. is a Delaware corporation with a place of business at 2400 North Commerce Parkway, Weston, Florida 33326, that Apotex Corp. is duly

authorized to do business in Delaware, and that The Corporation Trust Company is authorized to receive service of process on Apotex Corp.'s behalf. Apotex Inc. denies the remaining allegations of paragraph 5.

6. Upon information and belief, Apotex Corp. has availed itself of the legal protections of the State of Delaware, having filed counterclaims seeking judicial relief from this Court in, among other cases, *Sanofi-Aventis, et al v. Apotex Inc. et al*, Civil No. 07-792. Apotex Corp. has also admitted to personal jurisdiction in this court in the aforementioned action.

ANSWER: Apotex Inc. admits that Apotex Corp. has filed counterclaims in cases in this district, including Case No. 07-792, and that Apotex Corp. has not contested personal jurisdiction in the case. Apotex Inc. denies the remaining allegations of paragraph 6.

NATURE OF THE ACTION

7. This is a civil action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 100, et seq., and in particular under 35 U.S.C. § 271 (e). This action relates to a New Drug Application ("NDA") filed by Apotex with the United States Food and Drug Administration ("FDA") for approval to market a copy of sanofi-aventis' highly successful Taxotere® pharmaceutical products that are sold in the United States.

ANSWER: Apotex Inc. admits that this is an action alleging patent infringement pursuant to § 271(e) of the Patent Act and relates to NDA 22-312 filed by Apotex Inc. Apotex Inc. denies the remaining allegations of this paragraph.

JURISDICTION AND VENUE

8. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a):

ANSWER: Apotex Inc. admits that subject matter jurisdiction is proper.

9. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to Plaintiffs, which manufacture numerous drugs for sale and use throughout the United States, including this judicial district. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

ANSWER: Apotex Inc. waives only for the purposes of this action its objections to personal jurisdiction. Apotex Inc. otherwise denies the allegations of this paragraph.

10. This court has personal jurisdiction over Defendant Apotex Inc. by virtue of, *inter alia*, its systematic and continuous contacts with Delaware, including the substantial revenue it derives from the State of Delaware through its sister corporation and agent Apotex Corp, as well as its purposeful availment of this forum, such as its filing of claims and counterclaims in this jurisdiction.

ANSWER: Apotex Inc. waives only for the purposes of this action its objections to personal jurisdiction. Apotex Inc. otherwise denies the allegations of this paragraph.

11. This Court has personal jurisdiction over Defendant Apotex Corp. because it is incorporated under the laws of the State of Delaware, is registered to do business in the State of Delaware, and has a registered agent in the State of Delaware, and by virtue of, *inter alia*, its engaging in systematic and continuous contact with the State of Delaware, deriving substantial revenue from generic drugs consumed in the State of Delaware, as well as its purposeful availment of this forum, such as its filing of claims and counterclaims in this jurisdiction.

ANSWER: Apotex Inc. denies the allegations of this paragraph.

12. Venue is proper in this judicial district under 28 U. S.C. §§ 1391(c) and 1400(b).

ANSWER: Apotex Inc. waives only for the purposes of this action its objections to venue. Apotex Inc. otherwise denies the allegations of this paragraph.

BACKGROUND

13. Upon information and belief, Defendants have filed with the FDA in Rockville, Maryland, New Drug Application 22-312 ("the Apotex NDA") under 21 U.S.C. § 355(b)(2) (also known as a 505(b)(2) application) to obtain FDA approval for the commercial manufacture, use, and sale of a docetaxel injection product in the following dosage forms: 40 mg/ml, 20 mg/0.5 ml and 80 mg/2ml. Apotex filed its NDA No. 22-312 to obtain approval to market a generic forms of docetaxel injection solution, which is currently marketed by sanofi-aventis under the brand name Taxotere® (docetaxel) Injection Concentrate, before the expiration of certain sanofi-aventis patents, including U.S. Patent Nos. 5,438,072, 5,698,582, 5,714,512 and 5,750,561.

ANSWER: Apotex Inc. admits that Apotex Inc. submitted NDA 22-312 to the FDA pursuant to 21 U.S.C. § 355(b)(2) for docetaxel injection in 40 mg/ml, 20 mg/0.5 ml, and 80 mg/2 ml dosage forms and that NDA 22-312 seeks approval to market before the expiration of U.S. Pat. Nos. 5,438,072, 5,698,582, 5,714,512, and 5,750,561. Apotex Inc. denies the remaining allegations of paragraph 13.

14. On behalf of Apotex, Bernice Tao, as Director of Regulatory Affairs US for Apotex Inc., sent a letter dated June 27, 2008 to Plaintiffs to provide notice, pursuant to 21 U.S.C. § 355(b)(3)(B), that Apotex had filed NDA 22-312 with respect to docetaxel injection solution in a variety of dosage forms (40 mg/ml, 20 mg/0.5 ml and 80 mg/2ml). The letter further provided notice that Apotex had filed with the FDA, pursuant to 21 U.S.C. § 355(b)(2)(A)(iv), a certification ("Paragraph IV certification") alleging that U.S. Patent Nos. 4,814,470; 5,438,072; 5,698,582; 5,714,512; and 5,750,561 (collectively, "sanofi-aventis' patents") are invalid, not infringed, and/or not enforceable. The letter also included a statement of factual and legal allegations upon which Apotex based its certifications to the FDA.

ANSWER: Apotex Inc. admits that a letter dated June 27, 2008, was sent by Apotex Inc. to, *inter alia*, Plaintiffs to provide notice pursuant to 21 U.S.C. § 355(b)(3) that Apotex Inc. had filed NDA 22-312 with respect to docetaxel injection in 40 mg/ml, 20 mg/0.5 ml, and 80 mg/2 ml dosage forms. Apotex Inc. further admits that this letter provided Paragraph IV certification that U.S. Pat. Nos. 5,438,072, 5,698,582, 5,714,512, and 5,750,561 are invalid, unenforceable and/or not infringed by Apotex Inc.'s proposed docetaxel injection products, and that this letter

included a statement of factual and legal bases for Apotex Inc.'s assertions of invalidity, unenforceability, and/or noninfringement. Apotex Inc. denies the remaining allegations of paragraph 14.

APOTEX INC.'S FAILURE TO COMPLY WITH ITS OFFER OF CONFIDENTIAL ACCESS

15. In a letter dated June 27, 2008, Apotex offered sanofi-aventis confidential access to the Apotex NDA. Its offer of confidential access permitted one outside law firm to have access to the Apotex NDA for the purpose of determining if U.S. Patent Nos. 5,438,072, 5,698,582, 5,714,512 and 5,750,561 had been infringed by Apotex.

ANSWER: Apotex Inc. admits that in the June 27, 2008, letter Apotex Inc. offered to, *inter alia*, Plaintiffs confidential access to Apotex Inc.'s NDA 22-312 for the purpose of determining whether there is infringement and that the offer of confidential access was for the attorneys from one outside firm. Apotex Inc. denies the remaining allegations of paragraph 15.

16. Counsel for sanofi-aventis contacted Apotex on July 11, 2008 in an attempt to modify the offer of confidential access to allow for outside experts and one in-house counsel at sanofi-aventis to have access to the Apotex NDA.

ANSWER: Apotex Inc. admits that a person presumably acting for Plaintiffs sent a letter dated July 11, 2008, to Apotex Inc. and that the letter proposed certain conditions for confidential access to NDA 22-312. Apotex Inc. denies the remaining allegations of paragraph 16.

17. Almost two weeks later, on July 23, 2008, Apotex responded by email to the July 11, 2008, letter and proposed further modifications to the offer that would have prohibited outside experts from having access to the Apotex NDA.

ANSWER: Apotex Inc. admits that Apotex Inc. sent via E-mail a letter dated July 23, 2008, to a person presumably acting for Plaintiffs and that this letter proposed certain conditions for confidential access to NDA 22-312. Apotex Inc. denies the remaining allegations of paragraph

18. Counsel for sanofi-aventis responded to Apotex's July 23, 2008 email in a letter dated July 25, 2008, requesting that permission be given for one outside expert to review the Apotex NDA.

ANSWER: Apotex Inc. admits that a person presumably acting for Plaintiffs sent via E-mail a letter dated July 25, 2008, to Apotex Inc. and that the letter proposed certain conditions for confidential access to NDA 22-312. Apotex Inc. denies the remaining allegations of paragraph 18.

19. Apotex responded to sanofi-aventis on July 29, 2008 and allowed for an outside expert to have access to the Apotex NDA.

ANSWER: Apotex Inc. admits that on July 29, 2008, Apotex Inc. sent via E-mail to a person presumably acting for Plaintiffs a proposed agreement stating certain conditions for confidential access to NDA 22-312. Apotex Inc. denies the remaining allegations of paragraph 19.

20. On July 30, 2008, counsel for sanofi-aventis accepted Apotex's terms and faxed a signed offer of confidential access to Apotex.

ANSWER: Apotex Inc. admits that on July 20, 2008, a person presumably acting for Plaintiffs sent via E-mail to Apotex Inc. a document containing conditions for confidential access to NDA 22-312 signed by a person presumably acting for Plaintiffs. Apotex Inc. denies the remaining allegations of paragraph 20.

21. On Friday, August 1, 2008, counsel for sanofi-aventis contacted, by email and voicemail Ms. Eiko Yap, assistant to Apotex Vice President for Global Intellectual Property, Shashank Upadhye, to request that a countersigned copy of the offer of confidential access and the Apotex NDA be produced to counsel for sanofi-aventis. In two email messages from that day, counsel for sanofi-aventis included copies of the offer of confidential access regarding the Apotex NDA as signed by counsel for sanofi-aventis.

ANSWER: Apotex Inc. admits that on August 1, 2008, a person presumably acting for Plaintiffs sent an E-mail to Apotex Inc. requesting that Apotex Inc. send a signed agreement

concerning confidential access to NDA 22-312. Apotex Inc. denies the remaining allegations of paragraph 21.

22. Having not heard a response from Apotex, counsel from sanofi-aventis again contacted Ms. Yap by email on Monday, August 4, 2008, requesting production of a countersigned copy of the offer of confidential access and the Apotex NDA. In addition, counsel for sanofi-aventis contacted Mr. Upadhye directly by voicemail on the morning of August 4, 2008. In the email message to Ms. Yap from August 4, 2008, counsel for sanofi-aventis included a copy of the offer of confidential access regarding the Apotex NDA as signed by counsel for sanofi-aventis.

ANSWER: Apotex Inc. admits that on August 4, 2008, a person presumably acting for Plaintiffs sent an E-mail to Apotex Inc. requesting that Apotex Inc. send a signed agreement concerning confidential access to NDA 22-312. Apotex Inc. denies the remaining allegations of paragraph 22.

23. In a telephone call on the morning of August 5, 2008, Ms. Eiko Yap responded to counsel for sanofi-aventis and promised that the countersigned offer of confidential access and the Apotex NDA would be produced to counsel for sanofi-aventis as soon as possible.

ANSWER: Apotex Inc. denies the allegations of this paragraph.

24. In an email message from 11:29 PM on the night of August 5, 2008, Apotex Vice President for Global Intellectual Property, Shashank Upadhye, responded to the August 4, 2008 voicemail left by sanofi-aventis counsel and asserted that he would be unable to produce the countersigned offer of confidential access and the Apotex NDA because counsel had not specified a product name or molecule in his voicemail message from the morning of August 4, 2008.

ANSWER: Apotex Inc. denies the allegations of paragraph 24 except that Apotex Inc. admits that with respect to the purported message left on Mr. Upadhye's voicemail, at no point did Mr. Zerhouni identify who he was and what molecule or product name he was calling about. Prior

to the purported voicemail, Mr. Zerhouni had never contacted Mr. Upadhye directly. Apotex Inc. admits that Mr. Upadhye sent an email at about 11:29 pm on Tuesday, August 5, 2008.

25. Counsel for sanofi-aventis responded to Mr. Upadhye's August 5, 2008 message by an electronically delivered letter on August 6, 2008.

ANSWER: Apotex Inc. admits that on August 6, 2008, a person presumably acting for Plaintiffs sent via E-mail to Apotex Inc. a letter concerning confidential access to NDA 22-312. Apotex Inc. denies the remaining allegations of paragraph 25.

26. On the morning of August 8, 2008, on the eve of the expiration of the 45-day period for filing this action under the Hatch-Waxman Act and contemporaneous with the filing of this complaint, Apotex returned a countersigned offer of confidential access accompanied by 13 pages that purport to be a part of the Apotex NDA, which, in complete form, upon information and belief, runs into the many thousands of pages. Apotex's untimely and de minimis production of a portion of its NDA complies with neither its Offer of Confidential Access nor the requirements of 21 U.S.C. § 355(j).

ANSWER: Apotex Inc. states that the relevant date for expiration of the 45-day window was August 14, 2008. Apotex Inc. further states that the Offer of Confidential Access is governed by the provisions of 21 U.S.C. § 355(c)(3)(D) and not § 355(j); and furthermore, the statute specifically provides that any documents tendered may be redacted if not relevant. Apotex Inc. denies the remaining allegations of paragraph 26.

FIRST COUNT FOR INFRINGEMENT OF UNITED STATES PATENT NO. 5,714,512

27. The allegations of the preceding paragraphs 1-26 are repeated, realleged, and incorporated herein by reference.

ANSWER: Apotex Inc. incorporates by reference its answers to paragraphs 1-26.

28. United States Patent No. 5,714,512 B1 ("the '512 patent"), entitled "New Compositions Containing Taxane Derivatives" was duly and legally issued by the United States Patent and Trademark Office on February 3, 1998. Aventis Pharma S.A. is the owner by assignment of the '512 patent and has the right to sue for infringement thereof. A true and correct copy of the '512 patent is attached as Exhibit A.

ANSWER: Apotex Inc. denies the allegations of this paragraph.

29. Upon information and belief, Apotex's Paragraph IV certification alleged that its docetaxel injection product will not infringe claims 2-5, 8-12, 18-23, 28-31, and 34-35 of the '512 patent. Upon information and belief, Apotex's Paragraph IV certification alleged that all claims of the '512 patent are invalid.

ANSWER: Apotex Inc. admits that Apotex Inc. submitted a Paragraph IV certification alleging that, among other things, all the claims of the '512 patent are invalid and/or not infringed and in particular that Claims 2-5, 8-12, 18-23, 28-31, and 34-35 are not infringed and that all the claims are invalid in view of prior art.

30. Under 35 U.S.C. § 271(e)(2)(A), Apotex's submission to the FDA of NDA No. 22-312 to obtain approval for the commercial manufacture, use, or sale of its docetaxel injection product before the expiration of the '512 patent constitutes infringement of one or more claims of the '512 patent.

ANSWER: Apotex Inc. denies the allegations of this paragraph.

31. Upon FDA approval of NDA No. 22-312, Apotex will infringe the '512 patent by making, using, offering to sell, selling, and/or importing the docetaxel injection product in the United States, and by actively inducing and contributing to infringement by others under 35 U.S.C. §§ 271(b) and (c), unless this Court orders that the effective date of any FDA approval of Apotex's NDA shall be no earlier than the expiration date of the '512 patent.

ANSWER: Apotex Inc. denies the allegations of this paragraph.

32. Upon information and belief, Apotex's docetaxel injection product, when offered for sale, sold, and/or imported, and then used as directed, would be used in a manner that would directly infringe at least one of the claims of the '512 patent.

ANSWER: Apotex Inc. denies the allegations of this paragraph.

33. Upon information and belief, the use of Apotex's docetaxel injection product constitutes a material part of at least one of the claims of the '512 patent; Apotex knows that its docetaxel injection product is especially made or adapted for use in a manner infringing at least one of the claims of the '512 patent; and Apotex's docetaxel injection product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

ANSWER: Apotex Inc. denies the allegations of this paragraph.

34. Upon information and belief, the offering to sell, sale, and/or importation of Apotex's docetaxel product would contributorily infringe at least one of the claims of the '512 patent.

ANSWER: Apotex Inc. denies the allegations of this paragraph.

35. Upon information and belief, Apotex had knowledge of the '512 patent and, by its promotional activities and package insert for its docetaxel injection product, knows or should know that it will actively aid and abet another's direct infringement of at least one of the claims of the '512 patent.

ANSWER: Apotex Inc. denies the allegations of this paragraph.

36. Upon information and belief, the offering to sell, sale, and/or importation of Apotex's docetaxel injection product would actively induce infringement of at least one of the claims of the '512 patent.

ANSWER: Apotex Inc. denies the allegations of this paragraph.

37. Sanofi-aventis will be substantially and irreparably harmed by Apotex's infringing activities unless those activities are enjoined by this Court. Sanofi-aventis has no adequate remedy at law.

ANSWER: Apotex Inc. denies the allegations of this paragraph.

SECOND COUNT FOR INFRINGEMENT OF UNITED STATES PATENT NO. 5,750,561

38. The allegations of the preceding paragraphs 1-37 are repeated, realleged, and incorporated herein by reference.

ANSWER: Apotex Inc. incorporates by reference its answers to paragraphs 1-37.

39. United States Patent No. 5,750,561 B1 ("the '561 patent"), entitled "Compositions Containing Taxane Derivatives" was duly and legally issued by the United States Patent and Trademark Office on May 12, 1998. Aventis Pharma S.A. is the owner by assignment of the '561 patent and has the right to sue for infringement thereof. A true and correct copy of the' 561 patent is attached as Exhibit B.

ANSWER: Apotex Inc. denies the allegations of this paragraph.

40. Upon information and belief, Apotex's Paragraph IV certification alleged that its docetaxel injection product will not infringe any claim of the '561 patent.

ANSWER: Apotex Inc. denies the allegations of this paragraph.

41. Under 35 U.S.C. § 271(e)(2)(A), Apotex's submission to the FDA of NDA No. 22-312 to obtain approval for the commercial manufacture, use, or sale of its docetaxel injection product before the expiration of the '561 patent constitutes infringement of one or more claims of the '561 patent.

ANSWER: Apotex Inc. denies the allegations of this paragraph.

42. Upon FDA approval of NDA No. 22-312, Apotex will infringe the '561 patent by making, using, offering to sell, selling, and/or importing the docetaxel injection product in the United States, and by actively inducing and contributing to infringement by others under 35 U.S.C. §§ 271(b) and (c), unless this Court orders that the effective date of any FDA approval of Apotex's NDA shall be no earlier than the expiration date of the '561 patent.

ANSWER: Apotex Inc. denies the allegations of this paragraph.

43. Upon information and belief, Apotex's docetaxel injection product, when offered for sale, sold, and/or imported, and then used as directed, would be used in a manner that would directly infringe at least one of the claims of the '561 patent.

ANSWER: Apotex Inc. denies the allegations of this paragraph.

44. Upon information and belief, the use of Apotex's docetaxel injection product constitutes a material part of at least one of the claims of the '561 patent; Apotex knows that its docetaxel injection product is especially made or adapted for use in a manner infringing at least one of the claims of the '561 patent; and Apotex's docetaxel injection product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

ANSWER: Apotex Inc. denies the allegations of this paragraph.

45. Upon information and belief, the offering to sell, sale, and/or importation of Apotex's docetaxel product would contributorily infringe at least one of the claims of the '561 patent.

ANSWER: Apotex Inc. denies the allegations of this paragraph.

46. Upon information and belief, Apotex had knowledge of the '561 patent and, by its promotional activities and package insert for its docetaxel injection product, knows or should know that it will actively aid and abet another's direct infringement of at least one of the claims of the '561 patent.

ANSWER: Apotex Inc. denies the allegations of this paragraph.

47. Upon information and belief, the offering to sell, sale, and/or importation of Apotex's docetaxel injection product would actively induce infringement of at least one of the claims of the '561 patent.

ANSWER: Apotex Inc. denies the allegations of this paragraph.

48. Sanofi-aventis will be substantially and irreparably harmed by Apotex's infringing activities unless those activities are enjoined by this Court. Sanofi-aventis has no adequate remedy at law.

ANSWER: Apotex Inc. denies the allegations of this paragraph.

APOTEX INC.'S ADDITIONAL DEFENSES

First Additional Defense

Plaintiffs' Complaint fails to state a claim upon which relief can be granted.

Second Additional Defense

Plaintiffs are not entitled to relief because they are estopped by the prosecution histories for the asserted patents and subject to prosecution laches.

Third Additional Defense

The claims of the asserted patents are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation.

Fourth Additional Defense

Apotex Inc. does not infringe, and if marketed would not infringe, any valid and enforceable claim of the asserted patents with the products that are the subject of NDA 22-312.

Fifth Additional Defense

Plaintiffs' patents are unenforceable for inequitable conduct for reasons further explained below in Apotex Inc.'s Counterclaims, which are incorporated herein by reference.

WHEREFORE, Apotex Inc. hereby demands judgment dismissing Plaintiffs' Complaint with prejudice, judgment for costs and fees for suit, and for such other relief as the Court may deem just.

COUNTERCLAIMS

For its counterclaims against Plaintiffs and Counter-Defendants Aventis Pharma S.A. and sanofi-aventis U.S., LLC (collectively, "sanofi-aventis"), Defendant and Counter-Plaintiff Apotex Inc. states as follows:

Parties, Jurisdiction, and Venue

1. Apotex Inc. is a Canadian corporation with a place of business at 150 Signet Drive, Toronto, Canada M9L 1T9.

2. On information and belief, Aventis Pharma S.A. is a French corporation with its principal place of business in Paris, France. Sanofi-aventis U.S., LLC is a Delaware corporation with its principal place of business in Bridgewater, New Jersey, and each has a regular and established place of business in this district.

3. This action arises under the patent laws of the United States. Subject matter jurisdiction is proper in this Court pursuant to Title 28, U.S.C. §§ 1331, 1338(a), 2201, and/or 2202.

4. Personal jurisdiction is proper in this Court as to Aventis Pharma S.A. because it has subjected itself to the jurisdiction of this Court by virtue of filing its Complaint.

5. Venue is proper in this Court because sanofi-aventis has elected to file its Complaint in this Court.

Background

6. The United States Patent and Trademark Office issued U.S. Patent Nos. 5,714,512 ("the '512 patent"), 5,750,561 ("the '561 patent"), 5,438,072 ("the '072 patent"), and 5,698,582 ("the '582 patent"), naming Rhone-Poulenc Rorer S.A. as the assignee. On information and belief according to U.S. Patent Office records sanofi-aventis claims to have right, title, and interest in these patents.

7. On information and belief, sanofi-aventis is the current holder of approved New Drug Application ("NDA") No. 020-449 for a docetaxel injection product, which has the proprietary name Taxotere®.

8. The Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act require NDA holders to disclose to the FDA the patent numbers and expiration dates of those patents that the holders believe claim the "drug" for which their NDA is submitted, or patents covering a "method of using such drug." 21 U.S.C. §§ 355(b)(1) and (c)(2).

9. Sanofi-aventis listed the '512, '561, '072, and '582 patents in the publication "Approved Drug Products with Therapeutic Equivalence Evaluations," which is commonly called the "Orange Book."

10. Apotex Inc. submitted NDA 22-312 to the FDA pursuant to 21 U.S.C. § 355 (b)(2) for docetaxel injection in 40 mg/ml, 20 mg/0.5 ml, and 80 mg/2 ml dosage forms ("the Apotex products").

11. Apotex Inc. submitted to the FDA a certification, commonly called a "paragraph IV certification," that the '512, '561, '072, and '582 patents are invalid, unenforceable, and/or not infringed by the Apotex products.

12. In a written correspondence dated June 27, 2008, Apotex Inc. gave sanofi-aventis notice of said paragraph IV certification and such notice included an offer of confidential access as specified in 21 U.S.C. § 355(c)(3)(D).

13. In this action sanofi-aventis sued Apotex Inc. alleging infringement of the '512 and '561 patents. There has been and is now an actual and justiciable controversy between Apotex Inc. and sanofi-aventis as to whether the proposed docetaxel injection in products of NDA 22-312 infringe, induce infringement, or contribute to the infringement of any valid, enforceable claim of the '512 and '561 patents.

14. During prosecution of the '512 patent, there were 35 pending claims. In a rejection dated November 27, 1996, the U.S. Patent & Trademark Office ("PTO") rejected those pending claims over the prior art, which disclosed taxane formulations.

15. On February 24, 1997, the applicants for the '512 patent responded to the prior art rejection by arguing that the claim limitation "essentially free of alcohol" distinguished the prior art, because the prior art cited by the PTO "does not teach or suggest new solutions of Taxol derivatives such as those presently disclosed with less Cremaphor or ethanol" in order to avoid alcohol poisoning. That limitation was not in all of the pending claims.

16. After the applicants made this argument, the PTO then issued a notice of allowability on May 23, 1997. The notice expressly confirmed the PTO's reliance on the applicants' argument that the prior art did not have solutions "that do not cause anaphylactic shock or alcohol poisoning."

17. After the allowance, the applicants then sought to amend the claims to include the limitation "essentially free or free of alcohol." In a statement dated September 11, 1997, the PTO allowed the change and reported that the "claims will read free of alcohol."

18. Despite the applicants' argument and the PTO's requirement, applicants failed to modify all of the pending claims. Specifically, in an amendment dated October 20, 1997, applicants amended claims 1 through 23 to read "essentially free or free of alcohol," but applicants did not amend claims 24 through 35 to add this limitation.

19. Prosecuting a patent application is an *ex parte* process, and patent applicants are subject to the duties of good faith, candor, and disclosure, among others. *See* 37 C.F.R. § 1.56; Manual of Patent Examining Procedure (MPEP) § 2000.

20. The applicants' failure to amend claims 24 through 35 breached the duties of good faith, candor, and/or disclosure. Failure to amend claims 24 through 35 was material to patentability of the pending claims, particularly where the patent examiner already expressed the importance of the amendment to the patentability of these claims.

21. The '512 patent issued without including the required "essentially free or free of alcohol" claim limitation for claims 24 through 35. This resulted in claims 24 through 35 having an unfairly broader scope than claims 1 through 23. The broader scope should not have been allowed because inclusion of "essentially free or free of alcohol" was required by the applicants' argument and admissions and was the basis on which the PTO allowed the claims.

22. Upon information and belief, and based upon a reasonable inference due to the high materiality of the failure to amend pending claims 24 through 35 of the application that resulted in the '512 patent, the named inventors, prosecuting attorneys, patent assignees, Rhone-Poluenc Rorer S.A., sanofi-aventis, Aventis Pharma, and/or others substantially involved in the prosecution of these or related patents intentionally failed to amend claims 24 through 35 during prosecution of the '512 patent

23. Upon information and belief the '512 and '561 patents are unenforceable by reason of fraud and/or inequitable conduct arising from the applicants failure to disclose material prior art to the United States Patent and Trademark Office ("PTO") with an intent to deceive the PTO.

24. The '512 and '561 patents were pending before the PTO at the same time. Also at about the same time, the same applicants were prosecuting and had knowledge of the application process that resulted in the '072 patent and the '582 patent.

25. Upon information and belief, one or more of the same individuals at the relevant assignee entity were commonly involved in the preparation and/or prosecution of the '072 patent and/or the '582 patent, along with the '512 patent and/or '561 patent.

26. Nonetheless, the applicants failed to disclose in connection with the '512 patent very highly material prior art references that had been cited during the prosecution of the '561, '582, and/or '072 patents, namely, U.S. Patent No. 4,814,470 issued to Colin, U.S. Patent No. 4,534,899 issued to Sears, and U.S. Patent No. 5,254,580 issued to Chen. On information and belief according to U.S. Patent Office records U.S. Patent No. 4,814,470 was commonly owned with the other four Orange Book Patents: first by Rhone-Poulenc Rorer, then assigned to Aventis Pharma S.A. as were the other patents. The '470 patent is also listed in the Orange Book with the other four patents. In addition, applicants failed to disclose in connection with the '512 patent the following other references cited during the prosecution of the '561, '582, and '072 patents: U.S. Patent No. 4,507,217 issued to Sears; EPO 0118316; EPO 0253738; EPO 0522937; WO93/00928; WO93/00929; WO92/09589; WO93/16060; WO93/21173; WO94/12484; Chemical Abstracts 106, No. 22, abstract 182581c (1987); Agent, E. Rowinsky et al., "Taxol: A Novel Investigational Antimicrotubule," J. National Cancer Inst., v. 82, no. 15, at 1247-59 (1990); U.S. Patent No. 5,272, 171 issued to Ueda; Chemical Abstract vol. 106(22) 152581c Terry (1987); Chemical Abstract vol. 106(22) 182581c Tarr (1987); Merck Index, 11th Edition #7559 (1987); and Tarr "A New Parenteral Vehicle for the Administration of Some Poorly Water Soluble Anti-Cancer Drugs," J. Parenter. Sci. Technol. 41 (1), 31-33 (1987).

27. Similarly, the applicants failed to disclose in connection with the '561 patent very highly material prior art reference that had been cited during the prosecution of the '512, '582, and '072 patents, namely, U.S. Patent No. 5,254,580 issued to Chen. In addition, applicants failed to

disclose in connection with the '561 patent the following other references cited during the prosecution of the '512, '582, and '072 patents: U.S. Patent No. 4,507,217 issued to Sears; EPO 0118316; EPO 0253738; EPO 0522937; WO93/00928; WO93/00929; WO92/09589; WO93/16060; WO93/21173; WO94/12484; Chemical Abstracts 106, No. 22, abstract 182581c (1987); Agent, E. Rowinsky et al., "Taxol: A Novel Investigational Antimicrotubule," J. National Cancer Inst., v. 82, no. 15, at 1247-59 (1990); U.S. Patent No. 5,272, 171 issued to Ueda; Chemical Abstract vol. 106(22) 152581c Terry (1987); Chemical Abstract vol. 106(22) 182581c Tarr (1987); Merck Index, 11th Edition #7559 (1987); and Tarr "A New Parenteral Vehicle for the Administration of Some Poorly Water Soluble Anti-Cancer Drugs," J. Parenter. Sci. Technol. 41 (1), 31-33 (1987).

28. These undisclosed prior art references were material to patentability and were not merely cumulative. These undisclosed prior art references were important to patentability, a reasonable patent examiner would have considered them important to patentability, and these references contradicted or limited arguments made by the applicants during prosecution of the respective patent applications. Upon information and belief, these references were selectively disclosed in some but not all of the patent application files with an intent to deceive the PTO.

29. Section 2001.06 of the MPEP required applicants and other involved in the prosecution of these patents to bring to the attention of the PTO any material prior art or other information cited known to the applicant. The applicants' failure to disclose all pertinent prior art during prosecution of each of the '512 and '561 patents violated this Section and breached the duties of good faith, candor, and disclosure.

30. The applicants' failure to disclose all pertinent prior art during prosecution of the '512 and '561 patents was especially significant and material because the same patent Examiners

did not review and examine all of these patents. In fact, each patent was examined by a different examiner.

31. Upon information and belief, and based upon a reasonable inference due to the high materiality of failure to disclose all the pertinent prior art during prosecution, the named inventors, prosecuting attorneys, patent assignees, and/or others substantially involved in the prosecution of these or related patents intentionally failed to disclose all pertinent prior art that was known to them during prosecution of the '512 and '561 patents with an intent to deceive the PTO.

32. The fraud and/or inequitable conduct during prosecution of any one of the '512, '561, '582, and '072 patents infects and renders unenforceable some or all of the other patents.

33. This case is an exceptional one, and Apotex Inc. is entitled to an award of its reasonable attorneys' fees and costs under 35 U.S.C. § 285.

COUNT I

Declaration of Non-Infringement, Unenforceability and/or Invalidity of the '512 Patent

34. Apotex Inc. re-alleges and incorporates the allegations of all of the foregoing paragraphs of its Counterclaims.

35. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that no valid, enforceable claim of the '512 patent will be infringed by the manufacture, use, offer for sale, or sale of the Apotex products.

36. Sanofi-aventis asserts that the manufacture, use, offer for sale, or sale of the Apotex products do and will infringe claims of the '512 patent.

37. The manufacture, use, offer for sale, or sale of the Apotex products do not and will not infringe any valid, enforceable claim of the '512 patent, because the claims are unenforceable,

not infringed, and/or invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 or 112, or other judicially-created bases for invalidation.

38. A present, genuine justiciable controversy exists between Apotex Inc. and sanofi-aventis regarding the issue of whether the manufacture, use, offer for sale, or sale of the Apotex products would infringe valid, enforceable claims of the '512 patent.

39. Apotex Inc. is entitled to a declaration that the manufacture, use, offer for sale, and sale of the Apotex products do not and will not infringe any valid, enforceable claim of the '512 patent.

COUNT II

Declaration of Non-Infringement, Unenforceability and/or Invalidity of the '561 Patent

40. Apotex Inc. re-alleges and incorporates the allegations of all the foregoing paragraphs of its Counterclaims.

41. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that no valid, enforceable claim of the '561 patent will be infringed by the manufacture, use, offer for sale, or sale of the Apotex products.

42. Sanofi-aventis asserts that the manufacture, use, offer for sale, or sale of the Apotex products do and will infringe claims of the '561 patent.

43. The manufacture, use, offer for sale, or sale of the Apotex products do not and will not infringe any valid, enforceable claim of the '561 patent, because the claims are unenforceable, not infringed, and/or invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 or 112, or other judicially-created bases for invalidation.

44. A present, genuine justiciable controversy therfore exists between Apotex Inc. and sanofi-aventis regarding the issue of whether the manufacture, use, offer for sale, or sale of the Apotex products would infringe valid, enforceable claims of the '561 patent.

45. Apotex Inc. is entitled to a declaration that the manufacture, use, offer for sale, and sale of the Apotex products do not and will not infringe any valid, enforceable claim of the '561 patent.

COUNT III

Declaration of Non-Infringement, Unenforceability and/or Invalidity of the '072 Patent

46. Apotex Inc. re-alleges and incorporates the allegations of all the foregoing paragraphs of its Counterclaims.

47. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that no valid, enforceable claim of the '072 patent will be infringed by the manufacture, use, offer for sale, or sale of the Apotex products.

48. Sanofi-aventis has declined to give Apotex Inc. and its customers a covenant not to sue under the '072 patent.

49. This Count III of Apotex Inc.'s Counterclaims is an action to obtain patent certainty pursuant to 21 U.S.C. § 355(c)(3)(D) and 35 U.S.C. § 271(e)(5). This court has subject matter jurisdiction over this Count III that seeks a ruling concerning the invalidity, unenforceability and/or noninfringement of the '072 patent, which was listed in the Orange Book, but which is not the subject of an action by sanofi-aventis brought in 45 days after receipt of Apotex Inc.'s Paragraph IV notice, and with respect to which sanofi-aventis has declined to give a covenant not to sue.

50. The manufacture, use, offer for sale, or sale of the Apotex products do not and will not infringe any valid, enforceable claim of the '072 patent, because the claims are unenforceable, not infringed, and/or invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 or 112, or other judicially-created bases for invalidation.

51. A present, genuine justiciable controversy exists between Apotex Inc. and sanofi-aventis regarding the issue of whether the manufacture, use, offer for sale, or sale of the Apotex products would infringe valid, enforceable claims of the '072 patent.

52. Apotex Inc. is entitled to a declaration that the manufacture, use, offer for sale, and sale of the Apotex products do not and will not infringe any valid, enforceable claim of the '072 patent.

COUNT IV

Declaration of Non-Infringement, Unenforceability and/or Invalidity of the '582 Patent

53. Apotex Inc. re-alleges and incorporates the allegations of all the foregoing paragraphs of its Counterclaims.

54. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that no valid claim of the '582 patent will be infringed by the manufacture, use, offer for sale, or sale of the Apotex products.

55. Sanofi-aventis has declined to give Apotex Inc. and its customers a covenant not to sue under the '582 patent.

56. This Count IV of Apotex Inc.'s Counterclaims is an action to obtain patent certainty pursuant to 21 U.S.C. § 355(c)(3)(D) and 35 U.S.C. § 271(e)(5). This court has subject matter jurisdiction over this Count IV that seeks a ruling concerning the invalidity, unenforceability and/or

noninfringement of the '582 patent, which was listed in the Orange Book, but which is not the subject of an action by sanofi-aventis brought in 45 days after receipt of Apotex Inc.'s Paragraph IV notice, and with respect to which sanofi-aventis has declined to give a covenant not to sue.

57. The manufacture, use, offer for sale, or sale of the Apotex products do not and will not infringe any valid, enforceable claim of the '582 patent, because the claims are unenforceable, not infringed, and/or invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 or 112, or other judicially-created bases for invalidation.

58. A present, genuine justiciable controversy exists between Apotex Inc. and sanofi-aventis regarding the issue of whether the manufacture, use, offer for sale, or sale of the Apotex products would infringe valid, enforceable claims of the '582 patent.

59. Apotex Inc. is entitled to a declaration that the manufacture, use, offer for sale, and sale of the Apotex products do not and will not infringe any valid, enforceable claim of the '582 patent.

PRAYER FOR RELIEF

WHEREFORE, Apotex Inc. prays that the Court enter judgment in its favor and against Aventis Pharma S.A. and sanofi-aventis U.S., LLC as follows:

a) Granting a declaration that Apotex products do not and will not infringe any valid, enforceable claim of the '512, '561, '072, and '582 patents;

b) Granting a declaration that the claims of the '512, '561, '072, and '582 patents are invalid;

c) Granting a declaration that the '512, '561, '072, and '582 patents are unenforceable;

d) Declaring this an exceptional case in favor of Apotex Inc. and awarding attorneys' fees pursuant to 35 U.S.C. § 285;

e) Awarding costs and expenses; and

f) Awarding any and all such other relief as the Court determines to be just and proper.

Dated: August 27, 2008

DUANE MORRIS LLP

/s/ Matt Neiderman
Daniel V. Folt (Bar I.D. No. 3143)
Matt Neiderman (Bar I.D. No. 4018)
Aimee M. Czachorowski (Bar I.D. 4670)
1100 N. Market St., Suite 1200
Wilmington, DE 19801
302.657.4927

Of Counsel:

Richard T. Ruzich
Daniel R. Cherry
Richard W. McLaren, Jr.
Robert M. Gould, Ph.D.
DUANE MORRIS LLP
190 South LaSalle Street, Suite 3700
Chicago, Illinois 60603
(312) 499-6700
(312) 499-6701 (Fax)

Anthony J. Fitzpatrick
DUANE MORRIS LLP
470 Atlantic Avenue, Suite 500
Boston, MA 02210-2600
(857) 488-4220
(857) 401-3018 (Fax)